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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,142

11/10/2005

Richard Joseph Fagan

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER

SAOUD, CHRISTINE J

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

06/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,142	Applicant(s) FAGAN ET AL.	
	Examiner Christine J. Saoud	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66, 71-75 and 80-83 is/are rejected.
- 7) ☒ Claim(s) 67-70 and 76-79 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/3/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed 05 May 2008 has been received and entered. Claims 46-65 have been cancelled and claims 66-83 have been added. Applicant mistakenly identified claims 67-83 as having been added.

Election/Restrictions

Applicant's election without traverse of Group I, corresponding to claims 46 and 65 in the reply filed on 05 May 2008 is acknowledged.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The information disclosure statement (IDS) submitted on 03 October 2006 is in compliance with the provisions of 37 CFR 1.97 and has been considered by the examiner.

Drawings

The Drawings filed 02 June 2005 are acceptable.

Specification

The disclosure is objected to because of the following informalities: the table in the specification at page 56 includes nucleic acid sequences which do not have corresponding Sequence identifiers. 37 CFR 1.821 (d) requires

Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Appropriate correction is required.

If the nucleic acids in this table are not currently found in the Sequence Listing, Applicant will need to provide a new Sequence Listing (paper and computer copies) as well as a statement indicating that the two are the same and include no new matter. The sequences appear to be contained in the Sequence listing filed 10 November 2005, however, the specification still needs to be amended to include the Sequence identifiers in the table.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 66, 71, 73, 75, 80 and 82 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,914,046 (Hirsch et al.).

The instant claims are directed to isolated polypeptides and compositions thereof wherein the polypeptide has greater than 90%/95% sequence identity to SEQ ID NO:8 and wherein the polypeptide has “an activity of human growth hormone”. Hirsch et al. teach a protein which has 94.6% amino acid sequence identity to SEQ ID NO:8 of the instant application. The protein of Hirsch et al. would have at least immunogenic activity of human growth hormone based on the large regions of amino acid sequence identity.

It is noted that the calculated % identity is only 94.6%, which is not “greater than 95% sequence identity”. However, different algorithms used to calculate sequence identity are available and a slightly less conservative algorithm would provide a % identity that would be greater than 95% and meet the limitations of the instant claims. Therefore, the instant claims are anticipated by the prior art of Hirsch et al. absent evidence to the contrary.

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Sequence ID NO:8 compared to SEQ ID NO:2 of Hirsch et al.

Query Match 94.6%; Score 976.5; DB 2; Length 202;

Best Local Similarity 95.5%; Pred. No. 2.3e-100;

Matches 193; Conservative 0; Mismatches 6; Indels 3; Gaps 1;

Qy 1 MATGSRTSLLLAFLGLLCLPWLQEGSAFPTIPLSRLFDNAMLRAHRLHQLAFDITYQEF--- 57
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db 1 MATGSRTSLLLAFLGLLCLPWLQEGSAFPTIPLSRLFDNASLRAHRLHQLAFDITYQEFNPQ 60

Qy 58 VSSWGMESIPTPSNREETQQKSNLELLRISLLLIQSWLEPVQFLRSVFANSLVYGASDSN 117
 | ||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db 61 TSLCFSESIPTPSNREETQQKSNLELLRISLLLIQSWLEPVQFLRSVFANSLVYGASDSN 120

Qy 118 VYDLLKDLEEGIQTLMGRLEDGSPRTGQIFKQTYSKFDTNSHNDDALLKNYGLLYCFRKD 177
 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Db 121 VYDLLKDLEEGIQTLMGRLEDGSPRTGQIFKQTYSKFDTNSHNDDALLKNYGLLYCFRKD 180

Qy 178 MDKVETFLRIVQCRSVEGSCGF 199
 ||||||||||||||||||||

Db 181 MDKVETFLRIVQCRSVEGSCGF 202

Claims 66, 72, 74, 75, 81 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,013,773 (Kobayashi et al.).

The instant claims are directed to isolated polypeptides and compositions thereof wherein the polypeptide has greater than 90%/95% sequence identity to SEQ ID NO:10 and wherein the polypeptide has “an activity of human growth hormone”. Kobayashi et al. teach a protein which has 94.5% amino acid sequence identity to SEQ ID NO:10 of

the instant application. The protein of Kobayashi et al. would have at least immunogenic activity of human growth hormone based on the large regions of amino acid sequence identity.

It is noted that the calculated % identity is only 94.5%, which is not "greater than 95% sequence identity". However, different algorithms used to calculate sequence identity are available and a slightly less conservative algorithm would provide a % identity that would be greater than 95% and meet the limitations of the instant claims. Therefore, the instant claims are anticipated by the prior art of Kobayashi et al. absent evidence to the contrary.

Sequence ID NO:10 compared to SEQ ID NO:1 of Kobayashi et al.

Query Match 94.5%; Score 849.5; DB 2; Length 176;
Best Local Similarity 95.5%; Pred. No. 1.2e-88;
Matches 168; Conservative 0; Mismatches 5; Indels 3; Gaps 1;

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Qy      1 FPTIPLSRLFDNAMLRAHRLHQLAFDITYQEF--VSSWGMESIPTPSNREETQQKSNLEL 57
          |||||||||||||||||||||||||||||  |  |||||||||||||||||||
Db      1 FPTIPLSRLFDNAMLRAHRLHQLAFDITYQEFNPQTSLCFSESIPTPSNREETQQKSNLEL 60

Qy     58 LRISLLLIQSWLEPVQFLRSVFANSLVYGASDSNVYDLLKDLEEGIQTLMGRLEDGSPRT 117
          |||||||||||||||||||||||||||||||||||||||||||||||||||
Db     61 LRISLLLIQSWLEPVQFLRSVFANSLVYGASDSNVYDLLKDLEEGIQTLMGRLEDGSPRT 120

Qy    118 GQIFKQTYSKFDTNSHNDDALLKNYGLLYCFRKMDKQVETFLRIVQCRSVEGSCGF 173
          |||||||||||||||||||||||||||||||||||||||||||||||
Db    121 GQIFKQTYSKFDTNSHNDDALLKNYGLLYCFRKMDKQVETFLRIVQCRSVEGSCGF

176
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Allowable Subject Matter

Claims 67-70 and 76-79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Christine J Saoud/
Primary Examiner, Art Unit 1647
